



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CBER-05-009

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

WARNING LETTER

February 4, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Shelly R. Mullins
General Manager
Allergy Laboratories of Ohio, Inc.
623 E. 11th Avenue
Columbus, OH 43211

Dear Ms. Mullins:

The Food and Drug Administration (FDA) conducted an inspection of Allergy Laboratories of Ohio, Inc., 623 E. 11th Avenue, Columbus, OH, from November 1-4, 2004. During the inspection, the FDA investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 351 of the Public Health Service Act (PHS Act), 42 U.S.C. Section 262, and deviations from the applicable standards and requirements of Subchapter F, Parts 600-680, Title 21, Code of Federal Regulations (CFR). At the close of the inspection, FDA issued a Form FDA 483, Inspectional Observations, that described a number of significant objectionable conditions relating to the facility's compliance with current good manufacturing practice (CGMP). Significant deviations in the manufacture of allergenic source material observed during the inspection include, but are not limited to, the following:

1. You failed to follow current good manufacturing practices and applicable standards for the manufacture of allergenic source material [21 CFR 680.1(b)(2)(iii)]. On at least four occasions, you released mold source materials labeled as "non-viable mold mat," although your test records documented that final release testing demonstrated bioburden growth. The Certificates of Quality that were distributed with each of these source materials did not state the finished mold mats were positive for extraneous bacteria and mold contamination.
2. You failed to follow your established standard operating procedures (SOPs) [21 CFR 680.1(b)(2)(iii)]. Specifically, you did not repeat microbiological testing, as specified by your SOP [REDACTED] entitled "Mold Mat Viability and Bioburden Testing," when final release testing results exceeded your bioburden alert limit for four lots of mold source material.

3. You fail to maintain [REDACTED] conditions in your mold processing areas as specified by your SOP [REDACTED] entitled "[REDACTED]" [21 CFR 680.1(b)(2)(iii)]. Although you have a HEPA filtration system to provide the appropriate air quality in your mold processing areas, at the time of the inspection you regularly turned this system off on nights, holidays, and weekends, even though mold growth and incubation occur during these times. Your SOPs do not describe this practice, nor is there any data to support the actual room conditions during the time periods when the HEPA filtration system is shut down.

We acknowledge receipt of your written response, dated December 9, 2004, to the Form FDA 483. We have reviewed your response and the accompanying attachments. Corrective actions addressed in your December 9, 2004, response may be referenced in your reply to this letter, as appropriate. We have the following specific comments concerning your response. The items correspond to the observations listed on the Form FDA 483.

FDA 483 item #1

Your Certificate of Quality should be revised to include language that more accurately reflects the results of the viability/bioburden testing performed on the finished mold mats, including the level of bioburden and identification of any viable organisms isolated. In addition, we note you do not identify colonies that grow during viability/bioburden testing. Please be advised that viable organisms should be identified on your Certificate of Quality at least to the genus level for all isolates.

FDA 483 item #3

Your response does not address your failure to follow SOP [REDACTED] entitled "Mold Mat Viability and Bioburden Testing." Please provide specific details as to how you are addressing this observation.


Neither this letter nor the observations noted on the Form FDA 483 are intended to be an all-inclusive list of the deficiencies that may exist at your facility. It is your responsibility as a source material supplier to ensure that your operations are in full compliance with all applicable requirements of the federal regulations.

Please notify us in writing within 15 working days of receipt of this letter, of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Failure to promptly correct these deviations may result in regulatory action without further notice. Your response should be sent to Ms. Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852-1448.

Page 3 – Shelly R. Mullins, Allergy Laboratories of Ohio, Inc.

If you have any questions regarding this letter, please contact Ms. Anna M. Flynn in the Division of Case Management at (301) 827-6201.

Sincerely,


David K. Elder
Director
Office of Enforcement

cc: John A. Kuijper
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